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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/271,411	03/17/1999	M. ALLEN NORTHRUP	22660-0009P1	4121

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EXAMINER

MARSCHER, ARDIN H

ART UNIT	PAPER NUMBER
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1631

DATE MAILED: 03/06/2002

18

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/271,411

Applicant(s)
Northrup et al.

Examiner
Ardin Marschel

Art Unit
1631



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Nov 16, 2001
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 23, 25, 26, and 28-40 is/are pending in the application.
- 4a) ~~Of the above, Claim(s) 1-22, 24, 27, and 41-44 have been canceled.~~ ~~is/are withdrawn from consideration~~
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 23, 25, 26, and 28-40 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☒ The ~~proposed~~ drawing ^{correction} filed on 3/17/99 ^{me} is: ☒ approved ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- *See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
- 18) ☒ Interview Summary (PTO-413) Paper No(s). 15 & 17
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: _____

New grounds of rejection are summarized herein. Due to these new grounds of rejection, the finality of the office action, mailed 1/31/01, is hereby withdrawn. The amendment, filed 11/16/01, has been entered. The amendment, filed 8/6/01, which has been indicated as a previous form of the 11/16/01 amendment has not been entered as it is duplicated with added amending as desired by applicants in the amendment, filed 11/16/01. Due to this reopening of prosecution, the Notice of Appeal, filed 8/6/01, is deemed moot.

Applicants' arguments, filed 11/16/01, have been fully considered and they are deemed to be persuasive to overcome the previous rejections of record. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. Upon reconsideration, the following rejections and/or objections are newly applied. They constitute the complete set presently being applied to the instant application.

It is noted that applicants set forth amendments to the claims, filed 11/16/01, in a section entitled "IN THE CLAIMS:" wherein certain claims were amended as well as canceled. Confusingly for clerical processing, a separate section entitled "REMARKS" at the top of page 9 therein requests the cancellation of claims 41-44. In order to expedite the apparent cancellation request of applicants, claims 41-44 have been canceled. In the future, however, applicants are requested to include all claim

amendments with any claim cancellations in the one section entitled "IN THE CLAIMS:" in order to reduce the possibility of error due to missing amendments in the REMARKS section.

Claims 23, 25, 26, and 28-40 are rejected, as discussed below, under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 23 has been amended to include the last 3 lines as follows: "wherein the device is in combination with and designed to be inserted...". It is additionally noted that line 1 of claim 23 cites the phrase "A device for processing a sample, the device...". These lines cause the metes and bounds of claim 23 to be indefinite. The first line of claim 23 is reasonably interpretable as indicating that only a device is being claimed. This is also a possible interpretation of the last 3 lines of claim 23 in that a device "in combination with and designed to be inserted" may be interpreted as a device which may be inserted into a combination with an instrument in the future, but not necessarily inserted therein as claimed subject matter. An alternative confusing interpretation is that the device is presently in combination with an instrument as set forth in the last 3 lines of claim 23 and that the claimed subject matter is actually the device plus the instrument in a combination. This

latter interpretation is strengthened by the wording of claim 28 which depends from claim 23 but cites the "combination of claim 23" in line 1. Clarification is requested as to the metes and bounds of claims 23 and those dependent therefrom, such as claims 25, 26, and 28-37 regarding what device and/or combination is actually the required claim subject matter.

In claim 38, lines 3-16, the molding of a one-piece polymeric body is described "wherein the polymeric body is molded such that the reaction chamber, transition region, and separation region are formed in and enclosed by the body". This description of the molded body is not commensurate in scope with the specification, especially with the device as depicted in the Figures regarding the limitation "enclosed". Claim 38 and those dependent therefrom are thus vague and indefinite. The most direct interpretation of "enclosed" is that the molded body surrounds the reaction chamber, transition region, and separation region such that there are no openings which connects these regions and chamber to the outside of the body. The Figures, however, seem to depict openings. For example, in Figure 6 the reaction chamber (154) appears to be open at the top to the outside of the device. Also, the transition region (156) seems to be at least open to the outside via channel (184) and flow controller (182). Figure 5 depicts an opening from the separation region (108) to the right of item (114) to the

outside. Similar openings are present in Figures 3A - 3D. These Figures are described in the specification at various citations. It may be reasonably expected that the sample to be processed can be introduced into the device by some means such as an inlet port. No such inlet port, however, is cited in the claims. This inlet port practice, however, is not necessary if the sample is molded into the device during the production of the device. Consideration of claims 38-40, however, lacks any limitation or indication that any sample is molded into the device during device production. Therefore, are inlet ports utilized? If so, what is meant by the production of the device in claims 38-40 without requiring such expected inlet port inclusion in a molding process? Clarification of the metes and bounds of claims 38-40 which appear to not be commensurate with the specification and Figures as presently worded is requested. Should the "enclosed" limitation be interpreted to include partially enclosed? This is a possible interpretation of "enclosed" due to a lack of clarity as summarized above. It is also noted that the device and/or combination of claim 23 and claims dependent therefore also contain the above vague and indefinite phraseology given as the phrase "formed in and enclosed by the body" due to its presence in claim 23, part c).

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under

this section made in this Office action:

A person shall be entitled to a patent unless --

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 23, 28, 30-33, and 35-37 are rejected under 35 U.S.C. § 102(e) as being clearly anticipated by Handique et al. (P/N 6,130,098).

The abstract of Handique et al. discloses the central invention as being directed to the movement and mixing of microdroplets through microchannels in devices with reaction chambers, electrophoresis modules, etc. These elements are also summarized in column 3, line 49, through column 4, line 32, which includes various reaction and analysis practices. The use of electrodes positioned in a channel so as to move liquid when a potential is applied is disclosed in column 7, line 53, through column 8, line 44, which also described flow constricting means in such channels with dimensions in the range as required for instant claim 35. Various other flow constricting elements are present in the channels as noted in column 10, lines 57-65. In column 13, lines 19-34, a device of the invention includes reaction chamber, channels which serve as transition regions connecting said chamber, and an electrophoresis modules which is

a separation region where migration data is detected regarding electrophoretic separation. Such a separation via electrophoresis is further detailed in column 21, lines 35-67, including optics for detecting bands from said electrophoresis separation region as required in instant claim 28. This column 21 disclosure includes intercalating dyes which are deemed binding ligands for complementary nucleic acids in the sample being analyzed as also required in instant claim 33. These devices are microfabricated with the regions etc. therein reasonably interpreted as enclosed as described in column 3, line 65, through column 4, line 10, in an integrated system. Thermal conduction is limited in the device so that droplet movement can be controlled as noted in column 8, lines 1-9, via differential heating. The practice of a two part device with electrical pads as needed in a second or appliance type of element is disclosed in column 13, lines 49-59. The presence of heaters in the substrate are also described in a two part device as noted in column 18, line 40, through column 19, line 44. Side channels with flow control may also be utilized in the device (as in instant claim 36) of the invention as disclosed in column 14, line 24, through column 15, line 19, which also discloses air pockets as required in instant claim 31. Mixing of the sample droplets with reagents is also disclosed in column 16, line 62, through column 17, line 40, as also required in instant claim 37.

The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103(a).

Claims 23, 25, 28, 30-38, and 40 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Handique et al. (P/N 6,130,098), taken in view of Wilding et al. (P/N 5,587,128), or, alternatively, Wilding et al. (P/N 5,587,128), taken in view of Handique et al. (P/N 6,130,098).

Handique et al. has been summarized above as disclosing the basics of the instant invention focusing in particular on the practice of electrodes for movement of sample in microchannels between various chambers and/or regions of a microscale reaction/analysis device. Handique et al. utilizes

microfabrication for the production of the devices therein in microscale practice, but does not utilize polymeric materials molded for such device production.

Wilding et al. also describes devices and production thereof for microscale reaction/analysis practice and has previously been cited in the prosecution history of this application as citing reaction chamber, transition region, and separation region elements for such devices and therefore is of the same subject matter type as the above noted Handique et al. invention. It is noted that Handique et al. may be viewed to motivate the usage of electrode/voltage induced sample flow in channels as an improvement over Wilding et al., or, alternatively, the device microfabrication practice of Wilding et al. may motivate the usage of other materials which are equivalent for microfabrication of such devices as of the Handique et al. type. In Wilding et al. in column 7, lines 22-38, microfabrication of devices of this microscale or mesoscale type is suggested and motivated to be equivalently usable when made by silicon photolithography wherein the silicon may be polysilicon, polyimide, etc. as well as produced via plastic molding. Thus, a reasonable expectation of success in producing such devices and thus describing the devices per se is set forth for polymeric molding of devices of this type. It is noted that Wilding et al. also includes the immobilization of polynucleotide probes for

binding to target analyte in the separation detection region of such a device as noted in column 22, lines 13-27, as also required in instant claim 34.

Thus, it would have been obvious to someone of ordinary skill in the art at the time of the instant invention to either improve the Wilding et al. microscale devices and production thereof with electrode/voltage induced sample flow through channels as suggested in Handique et al., or, alternatively, produce or practice the electrode/voltage invention of Handique et al. with various microfabricated polymeric materials as equivalent as described in Wilding et al. to thus result in a reasonable expectation of success to practice the device and/or combination of device with appliance substrate of the instant invention or production thereof.

The reference by Knapp et al. (P/N 6,235,471) is cited on the enclosed PTO Form 892 due to being cumulative to Handique et al., described above. Knapp et al. also describes electrode usage for the transport of sample through microchannels as noted in column 5, lines 15-39, and column 10, lines 4-52, for various biochemical analyses and/or reaction practice.

No claim is allowed.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30

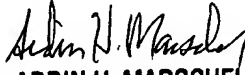
(November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The CM1 Fax Center number is either (703)308-4242 or (703)305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ardin Marschel, Ph.D., whose telephone number is (703) 308-3894. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (703)308-4028.

Any inquiry of a general nature or relating to the status of this application should be directed to Patent Analyst, Tina Plunkett, whose telephone number is (703)305-3524 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

March 1, 2002


ARDIN H. MARSCHEL
PRIMARY EXAMINER